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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,686	07/28/2003	Gabriele Lualdi	APV31644	4591

7590

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	10/627,686		LUALDI ET AL.	
	Examiner		Art Unit	
	Brian E Pellegrino		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-26 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 15, 16, 18, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-10, 13, 14, 17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9,24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites "the second coupling is of the conical type". Does this mean the first coupling is conical also since claim 1 recites the coupling means is conical? However, it appears there is only one conical coupling according to the drawings. Claim 24 recites the limitation "the cone" in lines 1 and 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

If the second coupling is only a conical coupling (which appears to be the case according to the drawings) then maybe the claim should recite "the pin forms a first cone and a conical cavity in the flange forms a second cone which when coupled together form the second coupling".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,6-9,13,14,17,19,21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ficat et al. (3064645) in view of Townley (6096084). Fig. 1 shows a

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femoral prosthesis with "substantially cylindrical" pin means **1** with a conical shape and a smaller end and a larger end where it is coupled to the head. Fig. 3 shows a removable femoral head **11** and coupling means **8** that is capable of being inserted into a seating of the femoral head via the upward projecting cylinder portion of the coupling means. Figs. 5-7 illustrate that the coupling means **8** comprise a flange **10**. Fig. 8 illustrates that the coupling means **8** is connected to the pin means via threaded portion **9**. Fig. 13 shows coupling means able to engage the top portion of the femur. It can be construed that the flanged insert is coupled eccentrically with the femoral head and the insert is fully capable of being cemented on the top of the femur. Ficat discloses inserting the stem or pin in the femur (Fig. 8) and then has the coupling means and head applied. It is inherent that the head is applied last since the apparatus is designed as removable and is implanted according to the patient's specifications or anatomical requirements, col. 2, lines 15-20. Ficat also shows (Fig. 13) a first portion or a mating cavity area that is capable of being coupled by a first coupling and the coupling being coaxial with the second coupling. However, Ficat et al. fail to disclose the coupling is of a conical type and that a seating is used to surround a top portion of the femur or the femoral head of a different material than the pin means. Townley shows (Fig. 8) a conical type coupling and the prosthesis surrounding the top portion of the femur. Townley teaches that the head and stem are made of different materials for structural purposes, col. 3, lines 35-39, col. 5, lines 53-63, col. 6, lines 53-61. It would have been obvious to one of ordinary skill in the art to use a conical coupling and also surround the femur as taught by Townley in the prosthetic femoral device of Ficat such that it is

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secured more and will not unattach since it surrounds the femur. A modification in the coupling means involves only routine skill in the art. It would have been obvious to one of ordinary skill in the art to use two different materials for the components such as ceramic for the head as taught by Townley with the device of Ficat such that it improves the articulation surface.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ficat et al. '645 in view of Townley '084 as applied to claim 8 above, and further in view of Callaway et al. (6736852). Ficat et al. in view of Townley is explained supra. However, Ficat et al. as modified by Townley fail to disclose the upper part of the housing in the flanged insert clamped to the pin means by a screw. Callaway et al. teach (Fig. 3a) a prosthesis with a screw **20** to be placed in an upper zone of housing **22** of a flanged insert **18** on a seating **14** to clamp together with pin means **12**. It would have been obvious to one of ordinary skill in the art to modify the coupling of the components and incorporate a screw as taught by Callaway et al. in the prosthesis of Ficat et al. as modified by Townley since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ficat et al. '645 in view of Townley '084 as applied to claim 1 above, and further in view of Pappas et al. (5030234). Ficat et al. in view of Townley is explained supra. Ficat does disclose the head is made of a cobalt alloy, col. 5, line 49. However, Ficat et al. as modified by Townley fail to disclose the pin means and the flanged insert being made of titanium. Pappas et al. teach that stems made of titanium are more flexible than cobalt

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alloys, col. 6, lines 53-61. It would have been obvious to one of ordinary skill in the art to modify the pin means and insert to be of titanium as taught by Pappas et al. in the prosthesis of Ficat et al. as modified by Townley since it will provide a more flexible stem to insert in the bone, but provides a strong articulating head.

Response to Arguments

Applicant's arguments filed 7/29/05 have been fully considered but they are not persuasive. Applicant argues that Ficat does not disclose the coupling means that is a flange insert. However, it is the Examiner's position that the "coupling means" of Ficat is clearly linking components together and does have flanged type structure. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F. 2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant also argues that Ficat's device functions differently, but fails to distinguish what features are lacking in the Ficat device as compared to the claimed invention. However, it should also be noted that "a coupling" has not been given any special definition and any type of connection or linking of components can clearly be said to be a type of coupling. Additionally, it would have been an obvious to one of ordinary skill in the art to modify the shape of the coupling to be conical as an obvious expedient. A change in shape is generally recognized as being within the level of ordinary skill in the art, absent any showing or unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E. Pellegrino